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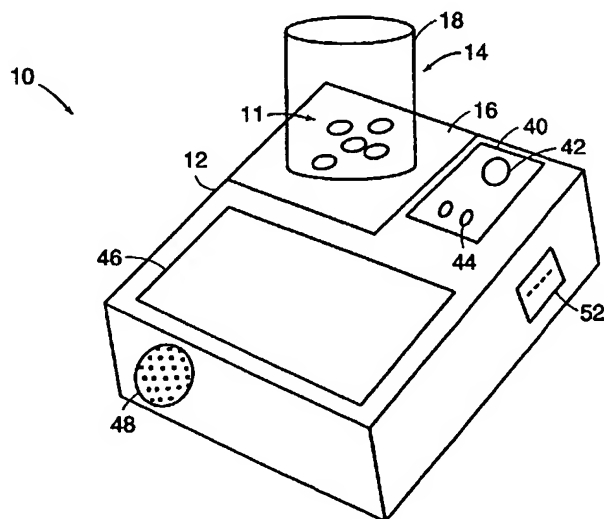
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(54) Title: PILL IDENTIFICATION AND PRESCRIPTION MANAGEMENT DEVICE, SYSTEM AND METHOD



(57) Abstract: A portable device inspects and identifies a pill or number of pills by analyzing the appearance of the pills. The device includes an imaging area and a digital camera for capturing an image of a batch of pills. The device includes a microprocessor and memory. A comprehensive reference pill database is stored in the memory. The pills are preferably identified by matching the appearance of each pill to a reference image or to related characteristics stored in the reference database. The device displays the relevant pill information. The reference pill database preferable also includes any other pill-related information that may be relevant to a patient, such a drug interaction information and special intake instructions. The device may also maintain patient database, including a historical record of pill identification sessions and prescription information. The device may also assist with ordering refills. In another aspect of the invention, the device may include a communication port or device such as a USB connector. A server maintains an updated reference pill database. The database is preferably accessible

through at least one web site and preferably through multiple websites. The reference pill database stored in the device can be updated from the database maintained on the server. In yet another aspect of the invention, a server maintains a database of patient information. The patient information preferably includes prescription information. The database may further include historical pill identification session records uploaded from the device. The database may be accessed from the portable device or a personal computer by either a patient or a health care professional. In yet another aspect of the invention, a comprehensive system for managing a patient's medication profile and monitoring the patient's pill intake is provided. The system maintains up-to-date information and is accessible to both patients and health care professionals.

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PILL IDENTIFICATION AND PRESCRIPTION MANAGEMENT DEVICE,
SYSTEM AND METHOD

FIELD OF THE INVENTION

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The invention relates to administering and managing medications for patients. More particularly, the invention relates to a device, system and method for managing and monitoring the prescribing and intake of prescription medications for a particular patient and a particular dose.

BACKGROUND OF THE INVENTION

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Greater numbers of people are using more drugs, especially prescription drugs, but also over-the-counter medications and herbal or other nutritional supplements, than ever before. This growth in drug intake has been fueled by many trends: a wider variety of medications are available; many former prescription medications are now available over-the-counter; direct-to-consumer advertising of prescription medications is growing; and media hype surrounding new medications and herbal supplements is substantial.

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Also, as more sophisticated treatments have developed for a variety of conditions, e.g., AIDS, patients are often prescribed complex drug regimens involving multiple medications that must be taken at various times and in various combinations throughout the day. Also, as our ability to diagnose illnesses and find treatments for them increases,

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many people are taking medications for illnesses formerly undiagnosed or thought untreatable. Further, the U.S. population is aging, and the elderly often use multiple medications and supplements for a number of problems. People are also taking "lifestyle enhancing" drugs for conditions that they used to "live with." Pills are one popular form for dispensing drugs; "pills" may include, for example, tablets, capsules, caplets, gel-

5 caps, liquigels, and softgels.

The proliferation of medications generally is a contributing factor to the large number of iatrogenic illnesses, i.e., illnesses that are caused by medical care itself, that affect patients every year, including illnesses that lead to hospitalizations.

“Polypharmacy,” the excessive prescription of multiple and interacting drugs, is a serious
10 issue. Medication-related iatrogenic illnesses may be caused by drug overdoses or otherwise incorrect dosages, incorrect medications, harmful drug interactions, missed doses or incorrect timing of doses. These illnesses may result because patients are confusing about their prescriptions, receive misfilled prescriptions, are forgetful regarding the quantity, type or timing of a dose, or misidentify a particular medication, miss an
15 expiration date, or mix pills in the same container. These problems further delay the delivery of effective treatment for medication-induced illnesses. Many of these problems, and thus the resulting illnesses, are very preventable. Even after they seek medical care for such an illness, patients may not be able to communicate what medicines they have taken or how much to emergency room personnel; they might not even remember what
20 medicines they are currently taking.

Patients taking medication generally experience less interaction with medical professionals regarding their drug regimens than in the past and less than they may need. Doctors and other health care professionals generally have less involvement with patients and less opportunity to oversee their drug intake than in the past. In the HMO age,
25 doctors have less time to spend with patients and doctors may focus on issues perceived as more critical during that time, leaving patients to sort out the details of their prescriptions with nurses and pharmacists or on their own. Patients may see a variety of different physicians or specialists, all of whom prescribe medications without being fully

5 aware of what other medications a patient is taking. Patients may continue on the same
medication for years without actually reevaluating their suitability with a health care
professional. Insurance companies are encouraging prescription refills through non-
traditional channels such as mail-order warehouses that keep costs down but further
reduce the human element in drug dispensing. Prescription drugs may even be prescribed
10 and ordered over the Internet, without any meaningful consideration of the patient's needs
by a health care professional. Insurance companies are also pressuring doctors to
prescribe less expensive drugs and to substitute generic drugs for brand name drugs, so
patients who are familiar and comfortable with a particular form of a pill may suddenly
find themselves with drugs that look substantially different from what they are used to.
15 "Pill books" that provide a comprehensive catalog of pills are large and unwieldy and not
necessarily helpful. They quickly become out-of-date.

Medical professionals may also make errors in dispensing medications. Again,
although pills come in a variety of shapes, sizes, and colors, many pills look very much
alike. Pills containing different doses of the same medication may look especially
20 similar. Medical professionals who work in medical institutions may handle a large
quantity of pills for a large number of patients each day. With such a large volume of
pills to administer, pills may get mixed up. In schools, nurses and even teachers are
administering a large number of prescription drugs (and even non-prescription drugs
because students are generally not allowed to self-medicate with any drugs at school) to
25 students during the school day.

For many prescription medications, despite the rigorous testing required for FDA
approval, certain side effects or drug interactions may not become known until the
medication is in widespread use. In such a case, the FDA will typically request

5 manufacturers to recall the medication, or will withdraw approval or issue public
advisories relating to the medication. Media channels are typically used to disseminate
this information. Information may often be spread by word of mouth between patients.
Patients may not receive the relevant information at all. Or if they do receive the
information, they may be confused by the information they receive and may wonder
10 whether reports they hear apply to them and to their medication and how to act on that
information.

The growth of the Internet and the World Wide Web has empowered patients to
seek health care information on their own. It is well-recognized that increasingly patients
are turning to the Internet for health-related information. Many web sites offer general
15 medical information and many others offer full services drug stores. Via the Internet,
patients can be active consumers of information rather than passive recipients of
information disseminated by more traditional media. With more information, consumers
can generally be better patients and better advocates for themselves in the health care
marketplace.

20 At least one means of pill identification has been disclosed that attempts to
address some of these issues. U.S. Patent No. 5,992,742 to Sullivan et al. issued on
November 30, 1999 and is entitled "Pill Printing and Identification." The disclosure
describes a machine readable bar code marking for pills and a medication dispenser that is
capable of reading the bar code and relaying the information to a computer. The machine
25 readable bar code is linked to identification, source, distributor, and expiration date
information. This system suffers from certain disadvantages, especially in that it requires
manufacturers to mark each pill with a special machine readable bar code; the limitations
imposed by the nature of the pills and by the scanning equipment dictate extensive criteria

5 for effective pill marking.

There is a need for a device that can assist patients with identifying pills and monitoring their intake of pills, and a system that can provide patients and doctors with up-to-date information regarding their prescriptions and historical pill intake records.

SUMMARY OF THE INVENTION

10 In one aspect of the invention, a portable device inspects and identifies a pill or number of pills by analyzing the appearance of the pills. The device includes an imaging area and a digital camera for capturing an image of a batch of pills. The device includes a microprocessor and memory. A comprehensive reference pill database is stored in the memory. The pills are preferably identified by matching the appearance of each pill to a
15 reference image or to related characteristics stored in the reference database. The device displays the relevant pill information. The reference pill database preferably also includes any other pill-related information that may be relevant to a patient, such as drug interaction information and special intake instructions. The device may also maintain a patient database, including a historical record of pill identification sessions and
20 prescription information. The device may also assist with ordering refills.

In another aspect of the invention, the device may include a communication port or device, such as a USB connector, and may be Internet ready or may connect to a personal computer. A server maintains an updated reference pill database. The database is preferably accessible through at least one web site and preferably through multiple
25 websites. The reference pill database stored in the device can be updated from the database maintained on the server.

In yet another aspect of the invention, a server maintains a database of patient

5 information. The patient information preferably includes prescription information. The database may further include historical pill identification session records uploaded from the device. The database may be accessed from the portable device or a personal computer by either a patient or a health care professional.

10 In yet another aspect of the invention, a comprehensive system for managing a patient's medication profile and monitoring the patient's pill intake is provided. The system maintains up-to-date information and is accessible to both patients and health care professionals.

BRIEF DESCRIPTION OF THE FIGURES

For a fuller understanding of the present invention, reference should be made to
15 the following detailed description taken in connection with the accompanying drawing which the same reference numeral indicate the same or similar parts:

Figure 1 is a perspective view of a pill identification device in accordance with one embodiment of an aspect of the present invention;

Figure 2 is a block diagram of the pill identification device shown in Figure 1;

20 Figure 3 is a diagram of a pill administration management and monitoring system in accordance with an embodiment of another aspect of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

An embodiment of a pill identification device 10 in accordance with one aspect of the present invention is shown in Fig. 1. The architecture of pill identification device 10 is
25 shown in Fig. 2. Device 10 is described with reference to Figs. 1 and 2. Device 10 allows a user to verify the identity of a pill or group of pills that may include different types of pills. Pill identification device 10 is contained within a compact housing 12. Pill

5 identification device 10 is preferably a small, portable device. Device 10 may optionally be mounted as a stationary device. Pill identification device 10 may be a hand-held device or approximately the size of a hand-held device. Pill identification device 10 will typically be used to identify no more than approximately 20-30 pills at once. Pill identification device 10 includes an imaging area 14 where the pills 11 to be identified are
10 placed for image capture by the device 10. Pill imaging area 14 may be a flat portion or tray in the upper surface of the device 10, with a viewing window 16 for the pill image to pass to the image capture device 20. Pills 11 may be placed directly on the viewing window 16 or a container 18 may be used to position pills 11 over viewing window 16. Alternatively, pill imaging area 14 may be a drawer or other compartment in device 10
15 with a viewing window oriented to allow a camera 20 to image pills 11. Viewing window 16 is preferably clear glass. In additional embodiments, imaging area 14 may have more than one viewing window. Multiple viewing windows are helpful for imaging the pills from a number of angles. For example, a top view may be useful. The viewing area is preferably illuminated with controlled illumination or strobe illumination to
20 maximize the quality for the image. Proper lighting may assist with robust object recognition.

In some embodiments, camera 20 is a digital camera. Digital camera 20 is positioned within housing 12 on the opposite side of viewing window 16 from pill imaging area. Digital camera 20 employs an electronic sensor 24, either a charge-coupled
25 device (CCD) or a CMOS detector. Lens 22 is positioned between viewing window 16 and electronic sensor 24 to focus the pill image and enhance the quality of the captured image. Digital camera 20 may alternatively incorporate multiple electronic sensors to capture images of pills 11 from a variety of angles and enhance the accuracy of device 10.

5 A light source 28 preferably illuminates pills 11 to be counted to further enhance the clarity of the captured images. The analog images captured in electronic sensor 24 are converted to digital images by an analog-to-digital converter 26. Digital camera 20 preferably employs Clarity 2 technology, a proprietary technology and trademark of Sound Vision, Inc. of Framingham, Massachusetts. In additional embodiments, camera
10 20 may be a scanning camera.

The captured image in digital form is transmitted from analog-to-digital converter 26 to a microprocessor 30 contained within housing 12. Microprocessor 30 processes the image, performing content analysis using pattern recognition and other techniques. Preferably, microprocessor 30 breaks the image down into its visual components and
15 separates the visual components into individual pills. Each pill image is further analyzed to extract pill identifying characteristics, including size, shape, color, texture, and markings. A reference pill database 34, including either pill images or pill characteristics or both, is stored in memory 32 contained within housing 12 and accessible to microprocessor 30. Memory 32 is preferably NVRAM. Microprocessor 30 compares the
20 captured image with the images stored in database 34. Microprocessor 30 may compare the image to stored images or may compare the extracted attributes with stored characteristic information, or use a combination of the two techniques, or use any other technique for image classification and matching. As described hereinbelow, reference pill database 34 can be updated.

25 Housing 12 includes a control panel 40. Control panel 40 includes a start button 42. Control panel 40 preferably includes an LED display 44 to indicate when device 10 is ready for a pill identification session and when the pill identification is complete.

The top of housing 12 includes a display window 46, preferably an LCD. If a pill

5 or several pills are identified, LCD 46 displays the relevant information, which for each type of pill may optionally include drug name (generic/brand name), manufacturer, dosage per pill, and total number of that type of pill. LCD 46 may also display, for example, any special instructions for taking the medications (e.g., "Take with food"), side effect warnings and the time for the next dose. If device 10 detects an unsafe drug
10 interactions, LCD 46 displays a warning. Device 10 optionally also includes an audio speaker 48 for transmitting the displayed content aloud. Device 10 also includes an alarm 49 to signal detection of a serious problem, such as an adverse drug interaction or a missed dose of an important medication. Control panel 40 could also include a keyboard-like or other input device 51. Alternatively, display window 46 could function
15 as a touch or light sensitive input device (e.g., a touch screen display) 51.

Device 10 also includes a real-time clock/timer 50. Device 10 may include a reminder function that signals, for example by flashing an LED or beeping or making an announcement aloud, that the patient should take the next dose. For convenience, it is preferred that power is supplied to device 10 by a battery so that device 10 is easily
20 portable; however, device 10 may also include a power cord to connect to an electrical outlet. A battery may also be provided as a back-up power supply. LCD 46 may also display battery charge level.

Device 10 is preferably a point-of-use device. Device 10 may be used by patients self-administering medication or by health care professionals or others administering
25 medication to patients. Device 10 is a tool for verifying what the patient is taking, including the type of pills, the total quantity of pills, and the total dosage. In operation, the user will place a number of pills 11, all of one kind or of multiple kinds, in one batch preferably only intended for a single patient, in pill imaging area 14. The user will enter a

5 patient identifier if necessary and then press a button 42 to initiate the identification process. Digital camera 20 will take and send the image or images of pills 11 to microprocessor 30. Microprocessor 30 runs software that operates the device 10. The device 10 will count and identify pills 11 using the image or images. Display 46 will show the pill name and number and any other related information, depending on the
10 user's preference settings. The device 10 will also check for negative drug interactions and for any other special conditions. If pills are detected that may harmfully interact with each other, or that may harmfully interact with pills taken by the patient within a certain window of time, device 10 will issue a text or audible warning.

In preferred embodiments, device 10 maintains a patient information database 36
15 organized by patient. Patient information database 36 includes a historical record of each pill identification session. If one device 10 is used to check medications for a number of patients, each patient may have a unique identifier so that device 10 may maintain separate records for each patient.

In preferred embodiments, patient information database 36 also maintains
20 prescription information for each patient using device 10. Such prescription information is useful for providing enhanced features through device 10. Device 10 may include a reminder function to remind patients to take medicines on a particular schedule. Device 10 may not only determine the identity of pills 11, but also confirm that the identified pills match the patient's prescriptions. In additional preferred embodiments, device 10
25 can also provide routine reminders relating to administration of the medications and relating to supervision of the patient's drug intake. For example, if the patient is required to have a monthly blood test while taking a particular medication, device 10 reminds patient at the appropriate time. Or device 10 counts down how many days are remaining

- 5 in a one-week prescription of antibiotics. Device 10 also informs the patient when a refill is advisable. The patient may enter prescription information into device 10 using input device 51 or by connecting device 10 to personal computer 68 and using software that provides an interface to device 10 through computer 68. The connectivity of device 10 is discussed further hereinbelow.
- 10 In preferred embodiments, device 10 is part of a comprehensive system 100 for providing pill management services in accordance with an additional aspect of the present invention. Device 10 preferably includes a communications port 52 or communications device 54. For example, device 10 includes USB port 52. Device 10 may connect to a printer for printing pill information, historical pill identification session records,
- 15 prescription summaries, warnings or any other desired information. Device 10 may also synchronize with a personal digital assistant, particularly to allow for calendaring of doses and refills. Device 10 may communicate with a personal computer or, alternatively, device 10 may communicate with a server 60, directly or through the Internet.
- 20 System 100 includes a server 60 that is remote from device 10. Server 60 maintains an up-to-date reference pill database 62. Reference database 62 includes pill images, pill characteristics, warnings and side effect information, drug interaction information, administration instructions, FDA recall and advisory information and any other information that may be useful for either identifying a pill or for administering
- 25 medications at point-of use. A service provider routinely updates reference database 62 preferably at least daily with any relevant information. Updates may include entries for new pills on the market, FDA recalls and advisories, etc. Different devices 10 may include or use different types of data to perform the same functions, depending on the

5 preferences and needs of the user. Information in reference database 62 may be broader than information in local device database 34 for any one device. When initiated by the user or at routinely scheduled times, device 10 will preferably link to server 60 (optionally through computer 68) and download the most current reference information from database 62, selecting the categories of information that are required for that

10 particular device 10. A Web site provided through a Web server, such as Web server 66, is a preferred interface for accessing server 60. Server 60 may also provide software upgrades that may be directly downloaded to device 10. Upgraded software may incorporate, for example, an improved pill identification algorithm or changes to the pill and patient database formats.

15 System 100 also includes a patient information database 64. In preferred embodiments, server 60 also maintains global patient information database 64. For every enrolled patient, server 60 maintains a record in the global patient information database 64. The global patient information 64 database is preferably organized using the same patient identifiers that are used to maintain patient records in local patient information

20 database 36 in device 10. The patient identifier may optionally be a universal health care identifier or insurance identifier. A patient record includes current prescription information. A patient record may also include historical prescription information. A patient record may also include a historical record of the patient's pill identification sessions and use of device 10. The global patient information database may be accessed

25 by the patient, through device 10, or using personal computer 68, to review prescription information or update prescription database. In addition to downloading information from server 60, device 10 can also upload information to server 60. Device 10 may synchronize patient prescription information with server 60. Device 10 may also transmit

5 historical pill identification session and device use records to database 64. Health care professionals may also access global patient information database 64 through a computer 69. Health care professionals may use global patient information database 64 to provide new prescriptions, to check the patient's drug regimen, to check what medications have been prescribed to a patient by multiple doctors, to check the patient's compliance with 10 their prescriptions, and to check what warnings and other information have been provided to patient. Emergency room personnel can quickly check a patient's prescription information through database 64.

Server 60 may also function as a clearinghouse for prescriptions. Rather than contacting a particular pharmacy or writing paper prescriptions, a doctor can simply enter 15 prescriptions into the global patient information database 64 on server 60 via a computer 69. Patients can access the prescriptions and have them filled at a traditional pharmacy or on-line pharmacy of their choice. Access to patient global information database 64 is preferably through web site 66.

In system 100, access to server 60 or to global patient information database 64 or 20 reference pill database 62 specifically may be provided through a particular "home" Web site on server 66 or alternatively through multiple host Web sites on servers 67, such as on-line health care sites, like WebMD.com, or on-line drugstores, such as drugstore.com. Device 10 may be set to automatically link to a particular Web server 66, 67 to access server 60, and, additionally, to order medications and refills from a particular Web site on 25 Web server 66, 67. Host Web sites may manage distribution of devices 10 and provide access to server 60 in order to encourage traffic at their sites.

The terms and expressions that have been employed herein are used for purposes of description and not of limitation. Although the invention has been described in

5 conjunction with specific embodiments, it is evident that many alternatives and variations will be apparent to those skilled in the art in light of the foregoing description.

Accordingly, the invention is intended to embrace all of the alternatives and variations that fall within the spirit and scope of the appended claims.

5 What is claimed is:

1. A pill identification device, comprising:
 - a digital camera;
 - a microprocessor;
 - a computer memory;
 - 0 a reference pill database stored in said memory;
 - said digital camera, said microprocessor, and said computer memory being stored within a portable housing.
2. A pill identification device in accordance with claim 1, further comprising a patient information database stored in said memory.
- 5 3. A pill identification device in accordance with claim 1, further comprising a viewing window.
4. A pill identification device in accordance with claim 1, further comprising a display panel.
5. A pill identification device in accordance with claim 1, further comprising a clock.
- 0 6. A pill identification device in accordance with claim 1, further comprising a speaker.
7. A pill identification device in accordance with claim 1, further comprising an input device.
8. A pill identification device in accordance with claim 1, further comprising a communications port.
- 5 9. A system for monitoring a patient's prescription medications, comprising:
 - a pill identification device, said device including a reference pill database;

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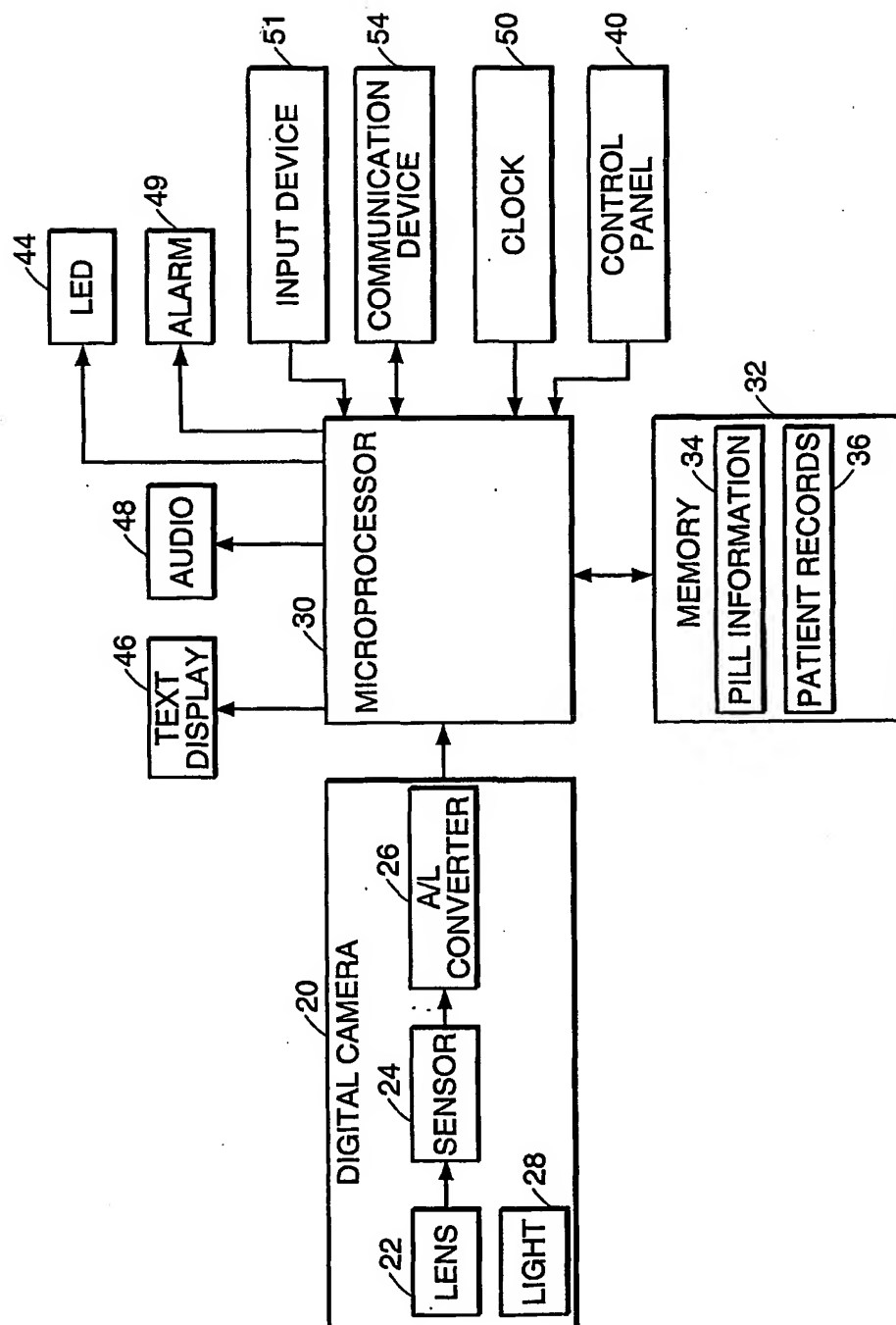


FIG. 2

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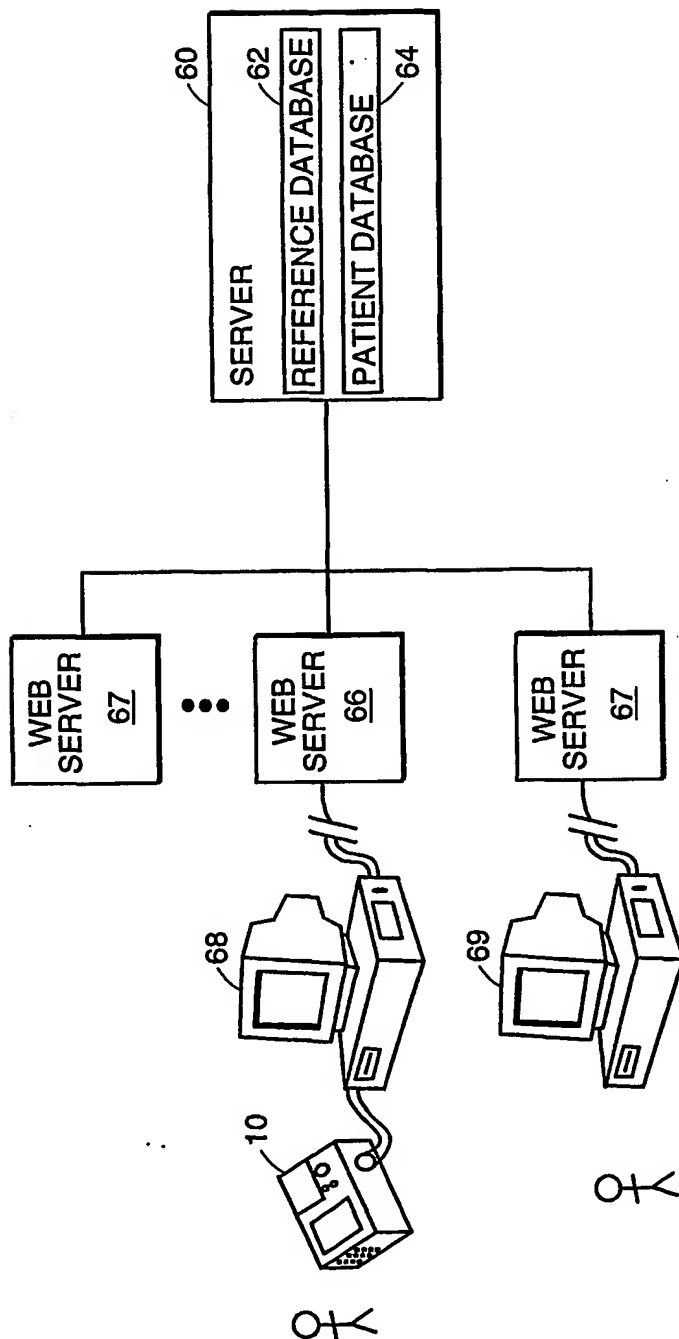


FIG. 3